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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/002,158 | 12/05/2001 | Wu-Bo Li | 0942.4750003 | 3737 |
| 26111 | 7590 | 02/25/2004 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | AKHAVAN, RAMIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,158

Applicant(s)

LI ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/13/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/25/2003 has been entered. The claims pending are 49-67. In addition applicant's Notice of Appeal, filed 09/25/2003 is acknowledged.

Response to Arguments

With regard to priority, as indicated in the Advisory Action, filed 10/01/2003, applicant has overcome rejections based on prior art, where rejections were based on Florkiewicz et al. (US 5,989,867) or Knappe et al. (US 6,028,058), due to perfection of the claim of benefit, for prior application, 08/103,769 filed on August 10, 1993 (Patent No. 5,500,356)..

Applicant's arguments with regard to after-final amendments are based primarily on language, "obtaining a sample comprising one or more single-stranded desired circular target nucleic acid molecules;" in the method for recovering desired circular target nucleic acid molecules. Put another way, amendments have narrowed target nucleic acids in obtained samples to *single stranded circular nucleic acids*. Therefore applicant asserts all prior art applied in the Final Action is distinguishable. (Remarks, 08/25/2003, pp. 10-14). All objections and rejections not repeated herein are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 49-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Base claim 49 recites the terms “desired” and “capturing”, which impart ambiguity and indefiniteness, viz., the claim’s metes and bounds. The specification only recites “desired” in the context of single-stranded target nucleic acid molecules (e.g. Spec. p. 6, ll. 20-25) or a desired target nucleic molecule that is both circular and single stranded (e.g. Spec. p. 9, ll.17-27). The claim is unclear, because as written, the phrase, “desired circular target nucleic acid molecules”, confers a meaning that certain circular molecules are more preferred than others, based on some undefined criteria. It would be remedial to simply delete the term as it does not add anything definite to the claim.

Claim 58 recites the limitation "said desired circular target nucleic acid molecule are double stranded DNA molecules". There is insufficient antecedent basis for this limitation in the claim. The claim is dependent from base claim 49, which does recite in the preamble one or more desired circular target nucleic acid molecules but then delimits such molecules to “single-stranded” molecules (subpart A). It is unclear how the desired molecule can be both single-stranded and double-stranded concurrently, which is exactly what claim 58 would require.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

- 2. Claims 49-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 7, 11, 15-17, 20-27, 29, 32, 36 and 37 of U.S. Patent No. 5,759,778 ('778 patent).**

Instant claim 49 is drawn to a method of obtaining one or more desired circular target nucleic acid molecules (CTDs), comprising obtaining a sample containing one or more CTDs, through a process of incubation with haptenylated probes containing sequence that hybridizes with CTDs, where the probe-target complex is pulled down via a hapten-specific ligand conjugated to a matrix. Subsequently, CTDs are released and treated to obtain double stranded DNA (dsDNA). Although not identical to instant claims, reference claims 1, 29 and 37 are drawn to indistinguishable subject matter. (cols. 13, 14 and 15 respectively).

More specifically, the reference claims are drawn to a method for recovering a desired target nucleic acid (ssDNA or dsDNA) from an initial mixture where the target is hybridized with a haptenylated nucleic acid probe and where the probe-target complex is captured using a ligand of the hapten, itself conjugated to a support with subsequent release to recover the target molecule. (reference claim 1). Additionally, single-stranded target can be hybridized with primers for template extension (reference claim 29) and resulting dsDNA can be used to transform a host cell (reference claim 37).

Essentially the pending claims are generic to the allowed claims and are therefore rendered obvious by them. The same analysis holds for the following pairs of pending claims to reference claims (pending:reference): 50:36, 37 (drawn to transforming host cell with dsDNA); 51: 1-2 (drawn to conditions for hybridization minimizing random hybridization); 52: 3-5 (drawn to target molecules being DNA); 53: 3, 7 (drawn to sample containing a mixture of DNA molecules); 54-57:15-17 (drawn to target molecules being plasmids, cosmids or phagemids); 58:11 (drawn to target being dsDNA); 59-66: 20-27 (drawn to hapten being biotin and ligands being avidin, streptavidin, antibodies or antibody fragments specific for biotin; in addition drawn to support being magnetic beads); and 67:32 (drawn to haptenylated probe having degenerate sequence). In each case the claims are drawn to patentably indistinguishable subject matter.

In summary, the claims of the '778 patent anticipate, thus necessarily make obvious, the broader claims from the instant application. In addition, if a patent resulting from instant claims were issued and transferred to an assignee different from the assignee for the '778 patent, then two different assignees would hold a patent to the subject matter of '778. Thus, improperly, there would be possible harassment by multiple assignees.

- 3. Claims 49-67 are rejected under the judicially created doctrine of double patenting over claims 1-13 and 17-20 of U. S. Patent No. 5,500,356 ('356 patent) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.**

Instant claim 50 and reference claim 1 is drawn to a method for obtaining an desired single stranded nucleic acid molecules, where biotinylated probes are hybridized with target nucleic acid molecules, with subsequent biotin-specific ligand pull down of the probe-target complex. Further, the target is released and primers are used to extend the single stranded template into dsDNA (reference claims 1, 19-20).

Essentially the pending claims are generic to the allowed claims and are therefore rendered obvious by them. The same analysis holds for the following pairs of pending claims to reference claims (pending:*reference*): 51:2 (drawn to hybridization under conditions to minimize random annealing); 52:6 (drawn to targets being DNA molecules); 53, 59:1 (drawn to the sample comprising a mixture of DNA molecules, and the hapten being biotin); 58:3, 6 (drawn to target molecules being dsDNA); 61-63:7-9 (drawn to the ligand being avidin or streptavidin); 66:11 (drawn to the support being paramagnetic beads).

One of ordinary skill in the art would have been motivated to examine the specification including the examples provided, to understand how to practice the claimed invention with respect to transformation of a host cell (e.g. *E. coli*) to propagate enriched isolated dsDNA. (e.g. instant claim 49-50, see '356 patent, col. 11, ll. 33-35; col. 12, ll. 66-67); with respect to ligands including biotin-specific antibodies and antibody fragments (instant claim 64-65, see '356 patent, col. 5, ll. 11-15); with respect to plasmids, cosmids or phagemids (instant claims 54-57, see '356

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patent col. 5, ll. 52-55); and with respect to binding biotin covalently to the probe nucleic acid (instant claim 60, see '356 patent, col. 7, ll. 57-62).

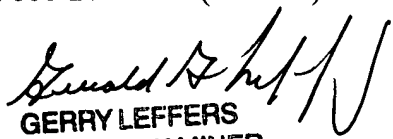
Therefore, the reference claims anticipate, thus necessarily make obvious, the broader claims from the instant application. In addition, if a patent resulting from instant claims were issued and transferred to an assignee different from the assignee for the '356 patent, then two different assignees would hold a patent to the subject matter of '356. Thus, improperly, there would be possible harassment by multiple assignees.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GERRY LEFFERS
PRIMARY EXAMINER